REMARKS

Applicants thank Examiner Ou for his time and consideration of the present application during the telephonic interview of February 7, 2011 with the undersigned.

During the interview the references were discussed, as well as proposed claims, from which the currently amended claims are based. As requested during the interview, a further feature concerning the plunger has been added to claim 1.

The claims have been amended in a manner to place the application in condition for allowance.

Status of the Claims

Claims 1, 5, 12, 16 and 17 are amended.

The amendment to these claims further defines the inner sheath as it relates to the implant (and movement thereof), outer sleeve, plunger and grip. Support for this portion of the amendment may be found, for example, at page 4 , lines 20-28; page 5, lines 7-14; page 8, lines 13-24; page 9, lines 6-12; page 9, line 17 to page 10, line 26. Also, the structure is shown in the Figures, such as Figures 9, 11, 13, 16 and 18

The amendment to claim 1 further includes additional features of the plunger itself. This amendment may be found, for example, at page 5, lines 8-10; page 9, lines 17-25; page 10, lines 20-25; and Figures 10, 11 and 18.

Claims 1, 4-10, 12-17 remain pending.

Claim Objections

Claims 1 and 4-17 were objected to because of the following informalities:

- In the fifth paragraph of claim 1, the phrase "push the edge of at the rear end";
- In the six paragraph of claim 1, a phrase "configured to be" should be inserted before the limitations "maintained by the internal wall of the inner sheath";
- In the seventh paragraph of claim 1, the limitation "to slide" should be corrected to "to be slidable";
- In the 7 paragraph of claim 17, the phrase "upon contact with the segment" is grammatically incorrect.

The claims have been amended to address these informalities, and withdrawal of the objection is respectfully requested.

Claim Rejections- 35 USC §112

Claims 1 and 4-17 were rejected under 35 USC §112, sixth paragraph, for failing the three-prong analysis test for the features: “means for opening the nose” in claims 1 and 10 and “means for translation” in claims 1 and 17.

Claims 1 and 4-16 were rejected under 35 USC §112, second paragraph for being indefinite with respect to the following features:

- In lines 2 and 5 of the fourth paragraph of claim 1: "the autoexpandable element";
- In the fifth paragraph of claim 1: the component of the device that the inner sheath is mounted; and
- In the seventh paragraph of claim 1: "at the end furthest from the intermediate section".

The amendments to the claims have clarified these features, and claim 1 is now definite.

Therefore, withdrawal of the rejection is respectfully requested.

Claim Rejections- 35 USC §103(a)

Claims 1-16 are rejected under 35 USC §103(a) as being unpatentable over LINDENGERG et al. US 5,433,723 ("LINDENBERG") in view of GARZA et al. US 4,665,918 ("GARZA") and MARTINEZ et al. US 5,593,412 ("MARTINEZ"). This rejection is respectfully traversed.

This combination fails to teach or suggest the claimed invention for several reasons with respect to the independent claims 1 and 17.

1. The Implant Structure

Claim 1 describes an implant (10) having (i) a first auto-expandable element (24), (ii) a second auto-expandable element (25) and (iii) a hollow intermediate section (26), which is deformable by twisting, is located between these two elements. The first auto-expandable element is positioned at a location closer to the nose (14) in the distal direction than the second auto-expandable element. These features are shown in figures 6, 11 and 18:

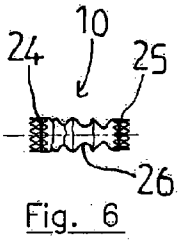


Fig. 6

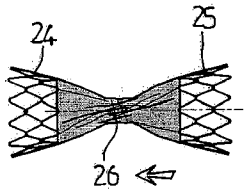


Fig. 18

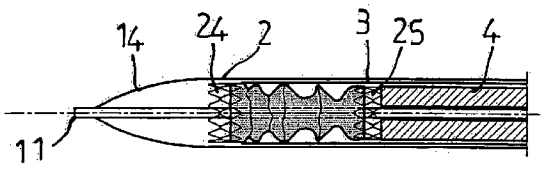


Fig.11

None of the cited documents teaches such an implant.

LINDENBERG utilizes an endoprosthesis (item 1 shown in Figures 3 and 8 below) made from a memory alloy (col. 2, line 13). This endoprosthesis may be formed from a sheet that is spirally wound, expanded metal with rhombic or honeycomb opening, a helically wound wire, cross woven fabrics or knitted fabrics:

Figure 3:

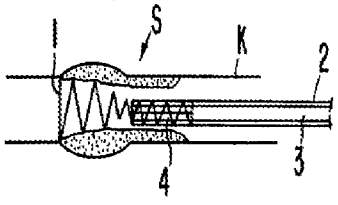
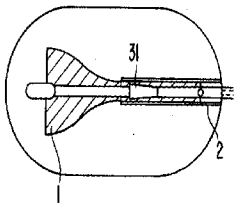


Figure 8:



There is no teaching of a twistable section between two expandable sections.

GARZA is limited to a prosthesis that is auto-expandable, but there is no suggestion of having a twistable/deformable section between the ends. See, e.g., item 5 in Figure 6 below:

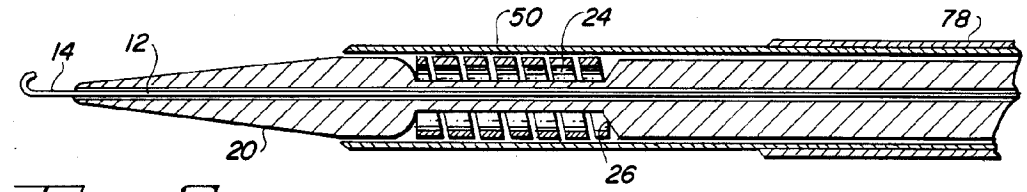
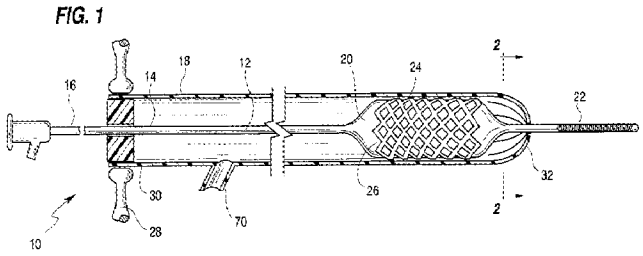


Fig-6

MARTINEZ discloses an implant (24) exapandable by an inflatable balloon (20) implant, e.g., shown below:



Thus, the combination fails to teach the implant structure of claim 1.

2. The Inner Sheath

Both independent claims 1 and 17 describe the inner sheath (3) has an internal wall for maintaining a portion of the implant (10), the inner sheath (3) being able to slide along the internal wall of the outer envelope (2) and being able to push this portion of the implant (10) so that the implant (10) moves in a distal direction toward the nose (14).

In claim 1, the second auto-expandable element (25) is configured to be maintained by the internal wall of the inner sheath (3), whereas in claim 17, the rear end is maintained by the inner sheath. In claim 1, the first auto-expandable element (24) is maintained by the internal wall of the outer envelope

(2), while in claim 17, the front end is maintained by the outer envelope. This is shown in Figures 11 and 13:

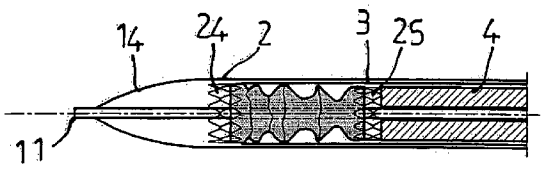


Fig.11

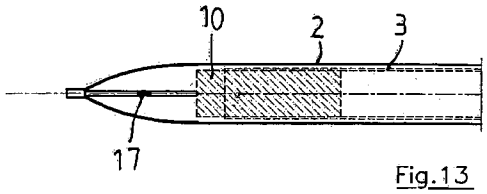


Fig.13

Consequently, when the outer envelope (2) is withdrawn in order to liberate the implant, only the auto-expandable element (24) will be in contact with the internal wall of the nose (14), as illustrated below:

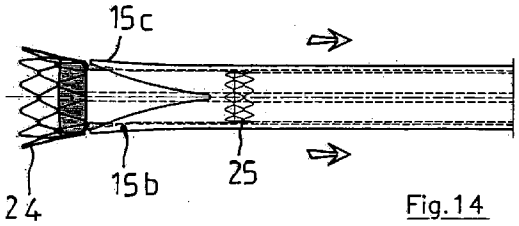


Fig.14

The inner sheath (3), by this longitudinal contact with the auto-expandable element (24), will contribute to rigidify the auto-expandable element (24) to allow the opening of the nose (see page 9 - line 1 to 5 of the specification).

This contact, at the edge of the element (24), is not suggested by the cited documents. That is, none of the cited documents suggests either of:

- a portion of an implanted maintained by an internal wall of the inner sheath and another portion maintained by the internal wall of the outer envelope, or
- an inner sheath being slidable within an outer envelope and able to push the rear end of an implant towards the distal end of the outer envelope to release the implant.

For example, in LINDENBERG, there is no inner sheath to constrain an implant. As shown in Figures 3 and 4 below, the helical structure may be constrained by an outer sleeve (2) and the tongues (4) of the applicator. The sleeve is retracted to expose the tongue and helical structure (column 4, line 64 to column 5, line 8 and column 6, lines 1-10):

Figure 3:

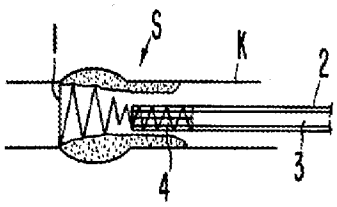
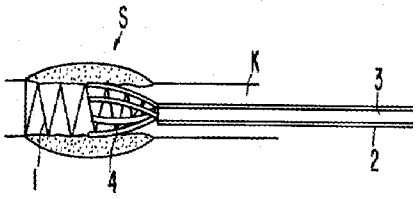


Figure 4:



GARZA discloses a device with a catheter 78 that covers the sheath 50, which constrains the prosthesis 25 (with portions 24 and 26) as shown below:

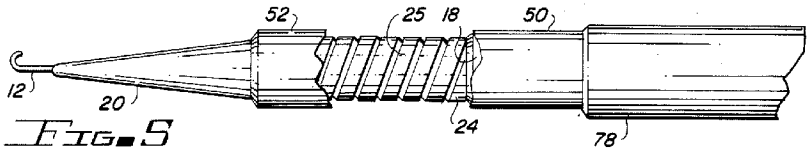


FIG. 5

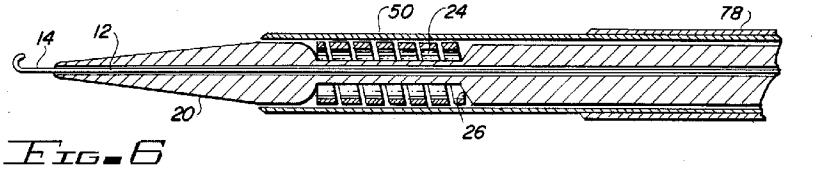
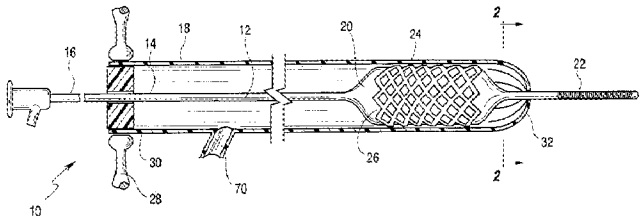


FIG. 6

However, one end of the prosthesis is not constrained by the sheath and the other end by the catheter. The implant is released by drawing back sheath 50, e.g., as explained relative to Figure 12a.

MARTINEZ does not disclose an inner sheath. MARTINEZ discloses an outer sheath, which constrains an implant (24) on a balloon (20), e.g., shown below:

FIG. 1



Indeed, the sheath is opened when exposed to warmth, such as a warm liquid injected in the sheath (col. 3, lines 29-42), not by any movement of an implant relative to the outer sleeve.

The operation is illustrated below in Figures 3-5:

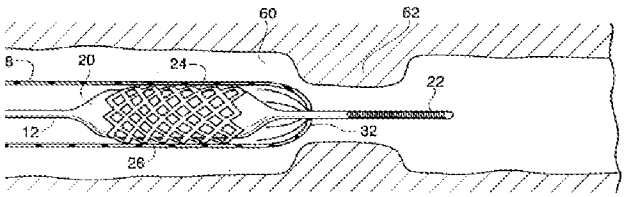


FIG. 3

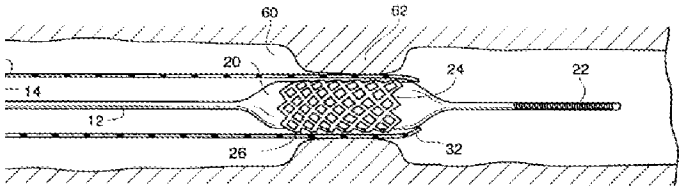


FIG. 4

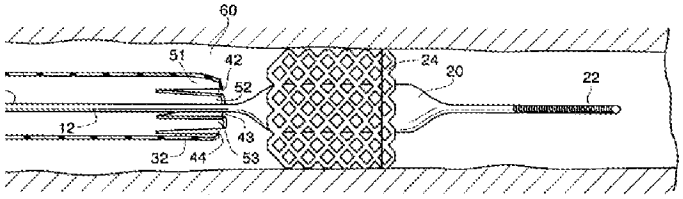


FIG. 5

Contrary to the conclusion held in the Official Action, the combination cannot teach utilization of an outer envelope in contact with the implant and an inner sheath slidable within the outer envelope, which contacts a different portion of the implant and is able to push the implant out of the outer envelope.

Indeed, at best, the combination suggests a sheath, such is in both LINDENBERG and GARZA, to release the implant by retracting the sheath, not by pushing.

3. Delivery of the implant

The implant of the claim 1 with its two auto-expandable elements at the two ends and the hollow intermediate section allows for a smooth delivery. When the outer envelope (2) is withdrawn, the auto-expandable element (24) presses against the inner wall of the nose leading to its opening. The auto-

expandable element (24) expands gradually functions of the nose opening.

Once the auto-expandable element (24) is expanded and pressed against the inner wall of the body cavity, the hollow intermediate section is delivered. The withdrawal of the outer envelope is easy since the hollow intermediate section which is not expandable does not press against the inner wall of the outer envelope. There is no risk that the implant be displaced.

In a similar way, claim 17 has a rear end of the auto-expandable implant pressed against the inner wall of the inner sheath and a front end that expands gradually to open the nose of the outer envelope.

This, however, is not the case with the LINDENBERG device in which the endoprosthesis which is expandable on all its length would press on the sleeve (2). At the beginning of the delivery, it is only a small portion of the endoprosthesis that presses on the inner wall of the body cavity. The biggest part of the endoprosthesis presses on the sleeve (2) or the applicator (3). Thereby, the force of the contact between the endoprosthesis and the inner wall of the body cavity could be weaker that the force of contact between the endoprosthesis and the device.

Additionally, the endoprosthesis of LINDENBERG would always have a part which would not press on the inner wall of the body cavity between the part already delivered that presses on

this inner wall of the body cavity and the part still in the device that presses on the sleeve or on the applicator.

Moreover, the proximal extremity of the endoprothesis of LINDENBERG has not a sufficient rigidity to open the nose mechanically.

In GARZA, there is no suggestion for opening the end of LINDENBERG, but instead GARZA only reinforces the concept utilized by LINDENBERG. Like LINDENBERG, the entire outer portion of the implant of GARZA is constrained by a sheath, which is retracted for release. Also like LINDENBERG, GARZA would always have a part which would not press on the inner wall of the body cavity between the part already delivered that presses on this inner wall of the body cavity and the part still in the device that presses on the sleeve or on the applicator.

With the device of MARTINEZ, the implant is expanded by the inflation of the balloon once the implant and the balloon are outside the sheath. If the balloon is inflated when implant is still inside the sheath in order to put in contact the implant and the nose, the implant could not be further delivered.

Accordingly, the combination of these three documents also fails to teach a structure similar to the claimed system to deliver the implant as suggested by the claimed structure.

4. The Twist Movement

The system of the claim 1 comprises an inner sheath

(3) which is able to rotate along the longitudinal axis of the device. Once the auto-expandable element is delivered and expanded, the practitioner can rotate the inner sheath relatively to the outer sleeve and the inner wall of the body cavity where the auto-expandable element (24) is fixed.

While the auto-expandable element (24) is fixedly maintained by its contact with the inner wall of the body cavity, the second auto-expandable element (25), still inside the device, is fixedly maintained in contact with the inner wall of the inner sheath. When the inner sheath rotates the second auto-expandable element (25) rotates relatively to the auto-expandable element (24) leading to a twist of the hollow intermediate section and a restriction.

LINDENBERG does not disclose the rotation of the applicator and the elements of the device are not able to rotate as described in column 5. In addition, it relates to an apparatus for widening a stenosis. Therefore, it would be useless and even be opposite to the aim of this document to twist the implant which inevitably leads to a decrease of the diameter of the implant.

Moreover, in order to produce a twist of the endoprothesis, the two extremities must be firmly maintained by two distinct parts. In LINDENBERG, one extremity of the endoprothesis is positioned on the body cavity and the other extremity is still positioned in the device by the tongues 4.

Nothing indicates that the tongues 4 have a sufficient contact surface with the endoprothesis to allow a rotation of the latter.

Also, the endoprosthesis described in LINDENBERG is not able to be twisted. This endoprosthesis is expandable along all its length that the force between the endoprosthesis and the inner wall of body cavity is weaker and does not allow a correct twisting of the endoprosthesis.

The device of GARZA does not suggest that the implant is able to twist. Indeed the implant is constrained between the sheath and features 20 as shown in the figure above.

The stent of MARTINEZ is expandable by an inflatable balloon going through the stent.

There is no means to allow a twist of the stent.

5. The Plunger

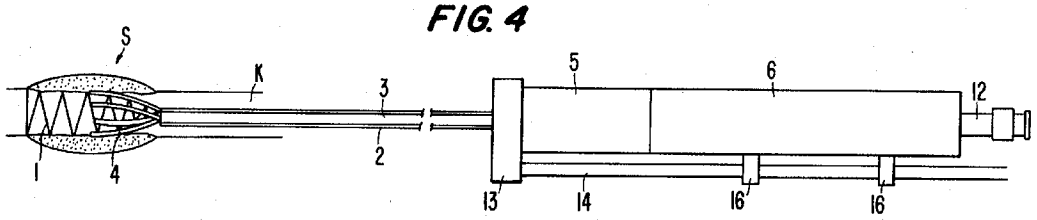
The claimed system comprises a plunger (4) mounted so as to slide in the inner sheath and can press against the free end of the second auto-expandable element (25). Like for the inner sheath and the auto-expandable element (24), the contact between the plunger and the second auto-expandable element (25) is longitudinal. The plunger applies on the edge of the second auto-expandable element (25). The second auto-expandable element (25) is maintained by the inner wall of the inner sheath (3). The plunger aims first at preventing the withdrawal of the implant

when the sleeve (2) is moved back and then at pushing out the implant in order to finalize its delivery.

The device disclosed by LINDENBERG is different from the invention. When, the sleeve (2) is withdrawn like the outer sheath of the present invention, the applicator (3) and the tongues (34) at its extremity are outside the sleeve (2), as well as the endoprosthesis on all its length.

The opening of the tongues outside the sleeve will partially liberate the endoprosthesis. Actually, when the endoprothesis is expanded, as shown in figure 4 below of LINDENBERG, its radially presses against tongues 4 which are trapped between endoprothesis and the inner wall of the body cavity:

FIG. 4



Therefore, if the endoprothesis is not sufficiently fixed to the inner wall of the body cavity, there is some risks that the endoprothesis is moved by the withdrawal of the device.

6. Combination with GARZA and MARTINEZ

To obtain the present invention of claims 1 and 17, one of ordinary skill in the art would only have placed in the sheath of MARTINEZ, the endoprosthesis and the applicator of LINDENBERG

considered as two combined and not separable elements, and further connected the sleeve of LINDENBERG to a grip as suggested by GARZA.

However, there is no hint in MARTINEZ that the sheath might be used to constrain an auto-expandable element, i.e., MARTIZEZ opens as a result of contact with warm fluid.

Moreover, even with the grip taught by GARZA there is no teaching of having an implant constrained at one end by the sheath of MARTINEZ and one end by the sleeve of LINDENBERG. Indeed, all three documents teach that when the implant is only partly constrained by a sheath (MARTINEZ and GARZA), and applicator (LINDENBERG) when exposed to the body, not prior to exposing the implant to the body, i.e., opening an outer envelope

Therefore, one starting from LINDENBERG could not have arrived at the claimed invention.

Therefore, the proposed combination cannot render obvious the claimed invention, and withdrawal of the rejection is respectfully requested.

Conclusion

In view of the amendment to the claims and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our credit card which is being paid online simultaneously herewith for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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